

November 9, 2006

**Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852**

**Re: Docket 2006N-0292
Advance Notice of Proposed Rule Making (ANPRM)
Unique Device Identification; Request for Comments**

Dear FDA,

Regeneration Technologies, Inc. would like to offer comments on the establishment of the unique device identification (UDI) system for medical devices. We are supportive of efforts to globally standardize medical device nomenclature and provide an automatic identification system.

We agree that a properly implemented UDI system will enhance patient safety and satisfy the needs of manufacturers and users. We believe it is imperative that FDA's UDI system be harmonized with global systems and regulations.

In particular we would like to bring the ISBT 128 standard to the Agency's attention. ISBT 128 is a global standard for the identification, labeling and information processing of human blood, tissue and organ products. This standard was adopted by the blood industry and is currently under consideration by the tissue industry. Because some medical devices contain a human tissue component it is essential that the proposed system be compatible with ISBT 128 requirements.

We would like to thank FDA for this opportunity to comment on the proposed rule making for the medical device unique identification system.

Sincerely,

**Lisa Simpson
Director, Regulatory Affairs
Regeneration Technologies, Inc.**